

REMARKS

Claims 29-43 are rejected. Claims 1-28 and 44-64 are withdrawn from consideration. Claim 29 has been amended. Claims 29-43 are presently pending in the application. Favorable reconsideration of the application in view of the following remarks is respectfully requested.

The basis for the amendment of claim 29 is found on page 6, lines 22-25 of the specification as originally filed.

Rejection Of Claims 29-43 Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 29-43 under 35 U.S.C. 103(a) as being unpatentable over Sutton et al. (4,997,772) in view of Pierce et al. (4,258,001), indicating that Sutton discloses a water insoluble polymeric particle having an inner core comprising a first polymer derived from one or more ethylenically unsaturated polymerizable monomers, and an outer shell comprising a second polymer derived from one or more ethylenically unsaturated polymerizable monomers, at least one of which monomers has reactive groups which are either directly or indirectly reactive with free amino or sulhydryl groups of an immunoreactive species, the particle having none of the tracer within the outer shell or on its outer surface, and the particle being covalently attached through the reactive groups on the outer surface to an immunoreactive species. The Examiner notes that the reference to Sutton discloses that the immunoreactive species attached to the particles can be enzyme, proteins or other biological compounds, that the first monomers have been disclosed, and also that the shell of the particles comprises a second polymers which can be represented by the formula (II) in that z can be 0 and F in the formula II of the reference is considered the claimed H of formula I in claim 36, representing vinylsulfonyl group; and the polymeric particles can be prepared using graft copolymerization to the external surface of said core. The Examiner states that the disclosure of the reference differs from the instant claims in that it does not disclose the particle composition comprising monodisperse polymer bead stabilized by vinylsulfonyl functionalized polymers, as in the claims, however, the reference does disclose the claimed core/shell polymeric particle in that vinylsulfonyl functionalized polymers are grafted to the external of said core and Pierce discloses organo-polymeric beads having a uniform size such as monodisperse beads stabilized by vinylsulfonyl functionalized polymers, making it would have been obvious to one

of ordinary skill in the art the use the core/shell polymeric particle composition, as disclosed in Sutton, to determine the monodisperse polymer beads stabilized by vinylsulfonyl functionalized polymers, as disclosed in Pierce, in order to gain the advantages of the combinations of the references, that being a particle composition comprising monodisperse polymer beads stabilized by vinylsulfonyl functionalized polymers which are grafted to the external surfaces of said beads, which has the added properties of being useful for the analysis of various substances in liquids, especially high MW proteinaceous substances in aqueous biological liquids using fluorescence Immunoassay element.

Sutton discloses a water-insoluble polymeric particle has an inner core comprising a detectable tracer material distributed in a first polymer for which the tracer material has a high affinity and an outer shell comprising a second polymer for which the tracer material has substantially less affinity relative to said first polymer. This second polymer contains groups which are either reactive with free amino or sulfhydryl groups of an immunoreactive species or which can be activated for reaction with such groups. Such a species can be covalently attached to this particle to form an immunoreactive reagent which is useful in analytical elements and various analytical methods including immunological methods, for example, agglutination assays. This invention relates to a core/shell polymer particle containing a detectable tracer material in the core only.

Pierce discloses an element for the analysis or transport of liquid, especially aqueous liquids, containing a structure comprising a plurality of heat-stable, organo-polymeric particles non-swellable in and impermeable to the liquid, and an adhesive concentrated at particle surface areas contiguous to adjacent particles bonding the particles into a coherent, three-dimensional lattice that is non-swellable in the liquid. These structures are particularly useful in the "dry chemistry" analysis of aqueous liquids. "Dry chemistry" analysis refers to analytical methods and techniques that are carried out using chemical reagents contained in various "dry-to-the-touch" test elements such as "dip-and-read" test strips, multilayer test elements and the like.

The present invention relates to a polymer particle comprising a monodispersed polymer bead stabilized by vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, grafted

to the surface of the bead, which are useful in a biological assay to allow a biological capture agent to be easily attached to the surface of such microspheres without using any chemical coupling agents and which allow the tag to retain higher reactivity than the same compounds bound directly to the surface of a similar bead. These particles are stable and dispersible in aqueous systems (pg. 6, lines 22-27) and, as indicated in the specification on pg. 3, lines 17-25, demonstrate enhanced reactivity of the immobilized target material.

To establish a *prima facie* case of obviousness requires, first, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

The reference to Sutton fails to teach the modification required by the present invention, that is, the monodispersed particles of the present invention and monodispersed polymer beads stabilized by vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, grafted to the surface of the bead, which are stable and dispersible in aqueous systems (pg. 6, lines 22-27) and, as indicated in the specification on pg. 3, lines 17-25, demonstrate enhanced reactivity of the immobilized target material. Pierce discloses a plurality of heat-stable, organo-polymeric particles non-swellable in and impermeable to the liquid for use in "dry chemistry" applications, not polymer particles that are stabilized by water soluble vinylsulfonyl-functionalized polymers. At best, the combination of the references would produce a water-insoluble particle, while the present particle, as a result of the grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, are stable in aqueous suspension. (pg. 18, line 1, Example 5, pg. 22, using a suspension of the inventive particles, and Example 6, pg. 23, using a solution of the inventive particles)

The reference also fails to provide any likelihood of success, as there is no teaching to suggest the preparation of monodisperse particles useful in

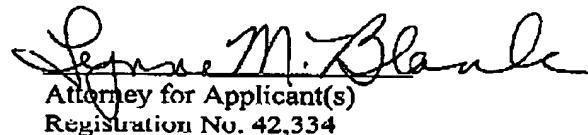
aqueous systems. Pierce and Sutton, as discussed above both teach water insoluble particles. The presently claimed particles, as a result of the presence of the grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, are stable in aqueous suspension. Pierce teaches the use of the particles in "dry chemistry" systems (col. 1, lines 8-15). Sutton specifically indicates the particles are water-insoluble (Abstract). Neither reference provides any likelihood of success in producing a water compatible particle for use in aqueous solution.

The references also fail to include all of the present claim limitations, since neither reference discloses or suggests grafted vinylsulfonyl-functionalized polymers, which are soluble in water, water-miscible solvents, or a mixture thereof, to produce particles that are stable in aqueous suspension.

In summary, the references fail to disclose, teach or suggest the present invention wherein a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, is grafted to the surface of the monodispersed polymer bead, fail to provide any likelihood of success for the use of monodispersed beads which are stabilized by a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, is grafted to the surface of the monodispersed polymer bead, resulting in the stability and dispersibility of these grafted polymer particle in aqueous systems, and fails to include the limitation that the polymer beads include a vinylsulfonyl-functionalized polymer, which is soluble in water, water-miscible solvents, or a mixture thereof, grafted to the surface of the monodispersed polymer bead. The Applicants therefore request that the Examiner reconsider and withdraw the rejection.

It is believed that the foregoing is a complete response to the Office Action and that the claims are in condition for allowance. Favorable reconsideration and early passage to issue is therefore earnestly solicited.

Respectfully submitted,



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-17-

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